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Reclast® receives US regulatory approval as first and only once-yearly treatment for women with postmenopausal osteoporosis

- *Shown to be highly effective in strengthening bones and protecting against osteoporosis-related fractures, including spine and hip*
- *Unique once-yearly dosing provides potential for significant compliance benefits*
- *Osteoporotic fractures affect one in two women over 50¹ and are associated with increased morbidity, mortality and healthcare costs*
- *European Union approval under brand name Aclasta® anticipated by end 2007*

Basel, August 18, 2007 – Reclast® (zoledronic acid) Injection has been approved by the US Food and Drug Administration as the first and only once-yearly medicine for postmenopausal osteoporosis, offering an important new approach to the treatment of a bone disease affecting eight million women in the US¹.

Unlike oral bisphosphonate therapies that have to be taken daily, weekly or monthly, Reclast is given as a once-yearly 15-minute intravenous (IV) infusion. This means with a single treatment, a patient can receive a full year's protection against the effects of osteoporosis – a disorder that causes bones to break easily.

“The fact that Reclast is highly effective and can be administered once-yearly represents a major milestone in the treatment of postmenopausal osteoporosis,” said Felicia Cosman, MD, Professor of Clinical Medicine at Columbia University in New York.

“For the first time we can ensure women receive a full year of the treatment they need to protect their bones,” said Dr Cosman.

The US approval comes a few weeks after the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion in July 2007 recommending approval for the medicine in the European Union, under the brand name Aclasta®. The European Commission generally follows the CHMP's recommendations and is expected to issue a final decision within three months.

The regulatory submissions were based on efficacy and safety data from the three-year Pivotal Fracture Trial, showing that Reclast increases bone strength and reduces fractures in areas of the body typically affected by osteoporosis, including the hip, spine and non-spine (e.g. wrist and rib)². Reclast is the only treatment proven to reduce fractures across all these key sites.

In this study involving more than 7,700 women, Reclast reduced the risk of spine fractures by 70% and hip fractures by 41% (*The New England Journal of Medicine*, May 3, 2007)².

The reduction in spine fractures was sustained over three years (60% in year one, 71% in year two, and 70% in year three). Bone mineral density increased significantly in the spine by 6.7% and in the hip by 6% in women on Reclast compared to placebo².

“Reclast has shown significant efficacy in protecting women against fractures in all the common osteoporotic fracture sites, while demonstrating a favorable safety profile,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “It is our hope that this innovative once-yearly dosing regimen will have a positive impact on the management of this potentially devastating condition.”

The need for effective treatments is pressing, with one out of every two women over age 50 suffering an osteoporotic fracture in her lifetime¹. The disease is responsible for 1.5 million fractures in the US every year¹, some of which have severe consequences. Approximately 20% of women over the age of 50 who suffer a hip fracture will die within one year¹.

Osteoporotic fractures are responsible for an estimated 800,000 emergency room visits, 500,000 hospitalizations, 180,000 nursing home placements, and 2.6 million physician visits in the US each year³, costing the healthcare system approximately USD 12.2 to 17.9 billion annually³.

“Osteoporosis is a serious disease affecting millions of people in this country,” said Leo Schargorodski, executive director of the National Osteoporosis Foundation (NOF). “NOF welcomes new FDA-approved treatment options, such as Reclast, that give patients a choice when it comes to taking their osteoporosis therapy.”

Reclast/Aclasta is approved in more than 60 countries including the US, Canada and the EU for the treatment of Paget’s disease, the second most common metabolic bone disorder. Additional studies are ongoing to examine the use of Reclast to prevent fractures following a hip fracture in men and women, treatment of corticosteroid-induced osteoporosis, and male osteoporosis.

The active ingredient in Reclast is zoledronic acid, which is also available in a different dosage under the brand name Zometa® (zoledronic acid 4 mg) Injection for use in certain oncology indications.

Reclast was found to be generally safe and well tolerated in clinical trials. In the Pivotal Fracture Trial an increased number of cases of serious atrial fibrillation were observed in women given Reclast compared to those on placebo (1.3% vs. 0.4% respectively)². However, this finding has not been observed in other clinical studies or in post-marketing experience with over 1.5 million patients treated with zoledronic acid for oncology indications. No spontaneous reports of osteonecrosis of the jaw (ONJ) – a rare occurrence in the osteoporosis population treated with bisphosphonates – were seen in the Pivotal Fracture Trial.

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The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as “potential”, “anticipated”, “generally follows”, “expected”, “hope”, “will”, or similar expressions, or by express or implied discussions regarding potential future regulatory approvals of Reclast/Aclasta, or potential future sales of Reclast/Aclasta. Such forward-looking statements reflect the current views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Reclast/Aclasta will be approved for sale, or for any additional indications or labeling in any market, or that Reclast/Aclasta will reach any particular level of sales. In particular, management’s expectations regarding Reclast/Aclasta could be

affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected additional analysis of existing clinical data, and unexpected new clinical data; competition in general; government, industry, and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; as well as the additional factors discussed in Novartis AG's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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References

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- 3 U.S. Department of Health and Human Services. Bone Health and Osteoporosis: A Report of the Surgeon General, 2004.

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